POLICY INTRODUCTION

The National Institute of Health (NIH) will be implementing the 2023 Data Management and Sharing (DMS) Policy with the new NIH Forms H Application Guide for **applications with receipt dates on or after January 25, 2023**. Under this policy, the NIH expects researchers to maximize the appropriate sharing of scientific data. The policy requires all applicants planning to generate scientific data to prepare a DMS Plan that describes how the scientific data will be managed and shared. The policy requirements include:

- **Submission** of a DMS Plan with all applications for funding with a deadline on or after January 25, 2023
- **Compliance** with the DMS Plan approved by the funding NIH Institute, Center, or Office

The plan should be two pages or less and address the following recommended elements:

- **Data type**: Identifying data to be preserved and shared
- **Related tools, software, code**: Tools and software needed to access and manipulate data
- **Standards**: Standards to be applied to scientific data and metadata
- **Data preservation, access, timelines**: Repository to be used, persistent unique identifier, and when/how long data will be available
- **Access, distribution, reuse considerations**: Description of factors for data access, distribution, or reuse
- **Oversight of data management and sharing**: Plan compliance will be monitored/ managed and by whom

A preview of this format page is available now (appended to this document), with a final fillable format version available by Fall 2022.

ACTIVITES SUBJECT TO THE POLICY

All research generating scientific data, including but not limited to:

- Research Projects
- Certain Career Development Awards (Ks)
- Small Business SBIR/STTR
- Research Centers

The policy does not apply to research projects not generating scientific data or non-research projects, including but not limited to:

- Training (Ts)
- Fellowships (Fs)
- Certain non-research Career Awards
- Construction (C06)
- Conference Grants (R13)
- Resources (Gs)
- Research-Related Infrastructure Programs (e.g., S06)

SCIENTIFIC DATA is defined as "the recorded factual material commonly accepted in the scientific community as **of sufficient quality to validate and replicate research findings**, regardless of whether the data are used to support scholarly publications."

STEPS TO BEGIN TAKING

1. **Consider the type of scientific data** your research will generate. The type(s) of data generated will inform many of the subsequent steps.

2. **Review FOAs and Identify a Repository**
    a. Certain FOAs will identify specific repositories or sets of repositories. For data generated from research subject to such policies or funded under such FOAs, researchers should use the designated data repository(ies).
    b. If NIH does not specify a repository, the NIH strongly encourages researchers to select a data repository that is appropriate for the data generated from the research project. There are over 70 NIH-supported repositories that may be applicable for the data type.

c. If no appropriate discipline or data-type specific repository is available, researchers should consider a variety of other potentially suitable data sharing options:
    1. Small datasets (up to 2 GB in size) may be included as supplementary material to accompany articles submitted to PubMed Central (instructions).
    2. Data repositories, including generalist repositories or institutional repositories, that make data available to the larger research community, institutions, or the broader public. Ensure the repository meets the desired characteristics by NIH.
        1. Consider using Texas Data Repository, which is free for UT researchers.
    3. Large datasets may benefit from cloud-based data repositories for data access, preservation, and sharing.

3. **Connect with the Repository** to understand if other tools are needed, the standards to be applied to scientific data and metadata, costs, how to register, how to upload, etc. Specific information related to tools and standards will be needed for the Plan.

4. **Begin drafting a DMS Plan** for your work based on the recommended elements (appended to this document).
    a. The plan should be **two pages or less**.
    b. The final, fillable format page will be available sometime in the Fall here.

5. **Consider using** DMPTool to draft your plan. DMPTool is suggested by UT Libraries to prepare plans for various funding agencies. DMPTool is free for UT researchers. See a blog and current instructions here. DMPTool also **offers template language** for drafting a NIH DMS Plan.

6. **Review Additional NIH Data Sharing Policies**
    a. Applications subject to NIH's Genomic Data Sharing (GDS) Policy should also address GDS-specific considerations within the elements of a DMS Plan (see NOT-OD-22-189).
    b. Many NIH Institutes and Centers have their own data sharing policies. See a complete list here. In the event that another applicable policy has more detailed expectations than that of the DMS Policy, those expectations should be followed in addition to the DMS Policy.

TIMING AND COST CONSIDERATIONS

- Under this policy, data will have to be **shared no later than the time of a publication of findings in a peer-reviewed journal OR at the end of the award**, whichever comes first.

- There is no standard rule for how long you must share the data. Consider
    - Data repository policies
    - Award record retention requirements
    - Journal policies

- DMS Plan Costs are allowable in the budget for certain allowable expenses as long as they are incurred during the award performance period:
    - Curating data
    - Preserving/sharing data through repositories
    - Local data management consideration

  *Connect with your departmental research administrator if you have additional questions about budgeting DMS Plan costs.

ASSESMENT OF DMS PLANS (not peer-reviewed)

- NIH program staff determine if your DMS Plan is acceptable or unacceptable.
- Peer reviewers ONLY consider if budget is reasonable.
- If revisions are needed, you will be able to do this through the standard Just-In-Time (JIT) process.

MONITORING COMPLIANCE

- Approved Plan becomes a Term and Condition of the award.
- Grantee reports progress of approved DMS Plan in the Research Performance Progress Report (RPPR) – Annual, Interim, and Final.
- NIH reviews compliance annually.
- Failure to comply may result in an enforcement action, including additional special terms and conditions or termination of award, and may affect future funding decisions.

ADDITIONAL RESOURCES

- Please find more detailed resources, including NOTs, FAQs, webinars and PPTs compiled by OSP here.
- Upcoming training: January 10th, 1-2PM via Zoom, OVPR/UT Libraries: "Data Management and Sharing Practices for NIH Funded Researchers and Beyond." RSVP here.
- NIH DMS Plan website and FAQs
- UT Libraries' Research Data Services can also assist you with multiple aspects of data management:
    - **Data Management Planning**: They can help explain funder policies and requirements for data sharing or data management plans. They can also meet with you to discuss and/or review your plan.
    - **Data Organization and Curation**: The Research Data Services team can help you develop and apply strategies for organizing and curating data through all phases of the research lifecycle. Connect to schedule a research data consultation meeting or workshop for your department or research group.
    - **Data Sharing and Publishing**: They provide advice about disseminating research data, ensuring that it is discoverable, accessible and reusable so that you can receive credit for your work. They can help you find the appropriate places to share your data openly, and help identify strategies for protecting sensitive information.
    - **Contact**: Michael Shensky, Head of Research Data Services, m.shensky@austin.utexas.edu
    - Assistance with Persistent Identifiers and creating DOIs can be found here.

FAQS

My award has ended, but I am not ready to publish. The policy requires me to share my data. How can I protect my data prior to publishing?

The NIH is currently considering this specific scenario. In the interim, the only option is to request a no-cost extension.

How do I protect my Intellectual Property (IP) under the DMS Plan?

The NIH understands that awards may lead to patentable results, however, the NIH does not see IP protection as a reason to limit sharing. More specifically, NIH advises researchers to consider the timing of data sharing and protection of IP to meet both the requirements under the policy and the desire to protect patentability. For example, one option is to apply for a provisional patent prior to publishing, which is advisable under the first-to-file policy. After filing a provisional patent application, share your data under the NIH DMS policy and publish your results. Starting at 32.42, you may review NIH's response to IP protection under the policy here.

Why can't I use Texas Data Repository for all my data?

If an FOA requires a specific repository, that repository must be used. If a repository is not specified, the NIH strongly encourages researchers to use a data-type specific repository, if available. If a data-type specific repository is not available, institutional repositories, like Texas Data Repository, are acceptable.

Why can't I share my data with my publication?

If an FOA requires a specific repository, that repository must be used. If a repository is not specified, the NIH strongly encourages researchers to use a data-type specific repository, if available. If a data-type specific repository is not available, small datasets (up to 2 GB in size) may be included as supplementary material to accompany articles submitted to PubMed Central (instructions).

Does this new DMS Policy apply to my current grant?

No. The NIH Data Sharing Policy NOT-OD-03-032, dated February 26, 2003, will remain applicable to proposals received prior to January 25, 2023, and contracts resulting from those proposals.

Do I need to share all my data?

No. Under the DMS Policy, researchers are expected to maximize the appropriate sharing of scientific data, which is defined as data commonly accepted in the scientific community as being of sufficient quality to validate and replicate the research findings.

A preview of the format page is appended on the following pages.

PREVIEW – DRAFT

DATA MANAGEMENT AND SHARING PLAN

If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on sharing.nih.gov. The Plan is recommended not to exceed two pages. Text in italics should be deleted. There is no "form page" for the Data Management and Sharing Plan. The DMS Plan may be provided in the *format* shown below.

Element 1: Data Type

A. Types and amount of scientific data expected to be generated in the project:
Summarize the types and estimated amount of scientific data expected to be generated in the project.

B. Scientific data that will be preserved and shared, and the rationale for doing so:
Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

C. Metadata, other relevant data, and associated documentation:
Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Element 2: Related Tools, Software and/or Code:
State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

Element 3: Standards:
State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist.

Element 4: Data Preservation, Access, and Associated Timelines

A. Repository where scientific data and metadata will be archived:
Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived; see Selecting a Data Repository).

B. How scientific data will be findable and identifiable:
Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

C. When and how long the scientific data will be made available:
Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

Element 5: Access, Distribution, or Reuse Considerations

A. Factors affecting subsequent access, distribution, or reuse of scientific data:
NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing. See Frequently Asked Questions for examples of justifiable reasons for limiting sharing of data.

B. Whether access to scientific data will be controlled:
State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).

C. Protections for privacy, rights, and confidentiality of human research participants:
If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

Element 6: Oversight of Data Management and Sharing:
Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).